EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph A. Fuchs on 02/11/08.

The application has been amended as follows:

In the specification:

At page 5, line 19, after the phrase "a portion of immediate release containing", the phrase "25%-75%, preferably" has been inserted.

At page 5, line 21, after the phrase "sustained release dosage containing", the phrase "25%-75%, preferably" has been inserted.

In the claims:

Claim 1, line 5, after the phrase "of the", the word "drugs" has been amended to "acetaminophen and tramadol".

Claim 1, line 5, the word "and" after the phrase "mini-tablets" has been deleted.

Claim 1, line 7, after the phrase "effective amount of the", the word "drugs" has been amended to "acetaminophen and tramadol".

Claim 1, last line, after the phrase "6% to 50%", the phrase "; and 3) the capsule releases 25%-60% of the acetaminophen and the tramadol in the first hour in a simulated gastric fluid dissolution media, 50%-90% of the acetaminophen and the

tramadol in the first four hours and not less than 80% of the acetaminophen and the tramadol in the first 12 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at 50 rpm" has been inserted.

Claim 5, line 5, after the phrase "effective amount of the", the word "drugs" has been amended to "acetaminophen and tramadol".

Claim 5, line 8, the word "and" has been deleted.

Claim 5, line 10, after the phrase "of the", the word "drugs" has been amended to "acetaminophen and tramadol".

Claim 5, last line, after the phrase "on the sustained release portion", the phrase "; and 3) the tablet releases 25%-60% of the acetaminophen and the tramadol in the first hour in a simulated gastric fluid dissolution media, 50%-90% of the acetaminophen and the tramadol in the first four hours and not less than 80% of the acetaminophen and the tramadol in the first 12 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at 50 rpm" has been inserted.

Claim 9, line 4, after the phrase "effective amount of the", the word "drugs" has been amended to "acetaminophen and tramadol".

Claim 9, line 9, the word "drugs" has been amended to "acetaminophen and tramadol".

Claim 9, last line, after the word "portion", the phrase "; and 3) the dosage form releases 25%-60% of the acetaminophen and the tramadol in the first hour in a simulated gastric fluid dissolution media, 50%-90% of the acetaminophen and the tramadol in the first four hours and not less than 80% of the acetaminophen and the

tramadol in the first 12 hours in a simulated intestinal fluid dissolution media using USP dissolution method II at 50 rpm" has been inserted.

Claims 2, 6 and 10 have been canceled.

The following is an examiner's statement of reasons for allowance:

The closest prior art, Raffa et al., do not teach the combination of both "acetaminophen and tramadol" in the immediate release as well as in the sustained release portions of the dosage form. The combination of the drugs, and the polymer in the claimed amounts result in the claimed release profiles that are not taught by Raffa et al.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 1, 3-5, 7-9, 11 and 12 are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner
Art Unit 1618